

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 6645-WO	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, Item 5 below.	
International application No. PCT/DK2004/000599	International filing date (day/month/year) 10/09/2004	(Earliest) Priority Date (day/month/year) 11/09/2003
Applicant NOVO NORDISK A/S		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 09 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. ☒ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☒ Certain claims were found unsearchable (See Box II).

3. ☒ Unity of invention is lacking (see Box III).

4. With regard to the title,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the drawings,

a. the figure of the drawings to be published with the abstract is Figure No. 1

☒ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/DK2004/000599

Box No. I Nucleotide and/or amino acid sequence(s) (Continuation of Item 1.b of the first sheet)

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, the international search was carried out on the basis of:
 - a. type of material
 - ☒ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☒ in written format
 - ☒ in computer readable form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed
 - ☐ filed together with the international application in computer readable form
 - ☒ furnished subsequently to this Authority for the purpose of search
2. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK2004/000599

Box II Observations where certain claims were found unsearchable (Continuation of Item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

Although claims 1-29 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of Item 3 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-29, 54-58

Use of GLP-1 agonists in the treatment of type 1 diabetes

2. claims: 30-46

Diagnosis of type 1 diabetes by analysing the concentration of endogenous GLP-1(7-37) and GLP-1(7-36) amide

3. claims: 47-53

Diagnosis of type 1 diabetes by analysing the level of HbA1c

INTERNATIONAL SEARCH REPORT

International Application No
PCT/DK2004/000599

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K38/26 G01N33/74 G01N33/72 A61P3/10

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, EMBASE, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
X	WO 95/31214 A (LONDON HEALTH ASS ; DUPRE JOHN (CA)) 23 November 1995 (1995-11-23) cited in the application the whole document	1-19, 27-29, 54-58
X	WO 00/42026 A (CORNELIS DE JONG JOHANNES ; KODRA JANOS TIBOR (DK); PETTERSON INGRID V) 20 July 2000 (2000-07-20) page 43, lines 5-7; claims 42-53,60,61	1-17, 54-58
X	WO 03/002136 A (NOVO NORDISK AS) 9 January 2003 (2003-01-09) page 10, last paragraph; claim 25 ----- -/-	1-23, 27-29, 54-58

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex

* Special categories of cited documents

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

A document member of the same patent family

Date of the actual completion of the international search

3 March 2005

Date of mailing of the international search report

30. 03. 2005

Name and mailing address of the ISA

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/DK2004/000599

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98/08871 A (NOVONORDISK AS ; KNUDSEN LISELOTTE BJERRE (DK); NIELSEN PER FRANKLIN ()) 5 March 1998 (1998-03-05) cited in the application page 5, lines 3-12; example 37	1-23, 27-29, 54-58
X	US 5 424 286 A (ENG JOHN) 13 June 1995 (1995-06-13) cited in the application column 2, lines 37-60	1-17, 24-29, 54-58
P,X	WO 2004/050115 A (NOVO NORDISK AS) 17 June 2004 (2004-06-17) claims 1,2	1-17, 24-29, 54-58
X	EP 0 201 187 A (NOVO INDUSTRI A/S; NOVO NORDISK A/S) 12 November 1986 (1986-11-12) page 2, lines 9-31 page 5, lines 15-18	47-53
X	OLSEN BIRTHE SUSSANE ET AL: "A 6-year nationwide cohort study of glycaemic control in young people with Type 1 diabetes: Risk markers for the development of retinopathy, nephropathy, and neuropathy" JOURNAL OF DIABETES AND ITS COMPLICATIONS, vol. 14, no. 6, November 2000 (2000-11), pages 295-300, XP002319816 ISSN: 1056-8727 the whole document	47-53
X	DANNE T ET AL: "Persistent differences among centers over 3 years in glycemic control and hypoglycemia in a study of 3,805 children and adolescents with type 1 diabetes from the Hvidovre Study Group." DIABETES CARE. AUG 2001, vol. 24, no. 8, August 2001 (2001-08), pages 1342-1347, XP002319817 ISSN: 0149-5992 the whole document	47-53
X	HOEY H ET AL: "Good metabolic control is associated with better quality of life in 2,101 adolescents with type 1 diabetes." DIABETES CARE. NOV 2001, vol. 24, no. 11, November 2001 (2001-11), pages 1923-1928, XP002319818 ISSN: 0149-5992 the whole document	47-53
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INTERNATIONAL SEARCH REPORT

International Application No

PCT/DK2004/000599

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
X	NORDLY S ET AL: "Quality of diabetes management in children and adolescents in Denmark." DIABETIC MEDICINE : A JOURNAL OF THE BRITISH DIABETIC ASSOCIATION. JUL 2003, vol. 20, no. 7, July 2003 (2003-07), pages 568-574, XP002319819 ISSN: 0742-3071 the whole document	47-53
A	VILSBOELL T ET AL: "EVALUATION OF BETA-CELL SECRETORY CAPACITY USING GLUCAGON-LIKE PEPTIDE 1" DIABETES CARE, AMERICAN DIABETES ASSOCIATION, ALEXANDRIA, VA, US, vol. 23, no. 6, June 2000 (2000-06), pages 807-812, XP000984497 ISSN: 0149-5992 the whole document	30-46

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/DK2004/000599

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

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